



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,003	09/11/2003	Se-Jin Lee	JHU1410-1	8520

7590 05/30/2007
Lisa A. Haile, J.D., Ph.D.
GRAY CARY WARE & FREIDENRICH LLP
Suite 1100
4365 Executive Drive
San Diego, CA 92121-2133

EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
----------	--------------

1637

MAIL DATE	DELIVERY MODE
-----------	---------------

05/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/662,003

Applicant(s)

LEE ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-27, 31-35, 40, 43-50, 55, 56 and 66-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-27, 31-35, 40, 49, 50, 55, 56 and 66-75 is/are allowed.
- 6) ☐ Claim(s) 43, 45 and 46 is/are rejected.
- 7) ☒ Claim(s) 44, 47 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 14, 2007 has been entered.

Preliminary Remark

Claims 1-24, 28-30, 36-39, 41, 42, 51-54, and 57-65 are canceled.

Claims 25-27, 31-35, 40, 43-50, 55, 56, and 66-75 are pending and are under prosecution herein.

Priority

It is **maintained** that the effective filing date of the instant application is determined to be November 10, 1997 (of the parent application serial no. 08/967,089).

Applicants traverse the denial of priority and contend that Applicants are entitled to the priority date back to October 26, 1995, corresponding to U.S. Application Serial No. 08/525,596 (now a U.S. Patent No. 5,827,733).

Applicants maintain that the parent application fully supports claims directed to a method for detecting the presence of a target myostatin variant nucleic acids sequence in a nucleic acid containing specimen, as the priority application provides support for the importance of a mature or C-terminal region of the myostatin polypeptide, where exon 3 and the specific 11 base-pair mutation are found (page 9, bottom, Response).

Applicants are respectfully requested to provide **factual** evidence wherein the instantly claimed mutation, that is G1056A substitution in Piedmontese and 937-947, is disclosed as the purported 11base pair mutation provided for in the parent application.

With Applicants' statement regarding that Applicants were the first to clone the bovine myostatin sequence which is provided in the priority applications as well as deposited in GenBank accession no. AF019620 (page 10, bottom paragraph, Response), unless the disclosed gene contains the claimed mutation itself, the disclosure of a wildtype gene does not provide support for a method of detecting for a particular phenotype based on a particular mutations found therein. Applicants are again requested to provide factual evidence which shows that the gene disclosed in the parent application does, in fact, contain the claimed mutation.

For the above reasons, the effective priority is properly determined and is accorded the date of November 10, 1997).

Claim Objections

The objection to claim 50 for containing a typographical error, made in the Office Action mailed on September 15, 2006 is withdrawn in view of the Amendment received on March 14, 2007.

Claim Rejections - 35 USC § 112

The rejection of claims 66-70 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on September 15, 2006 is withdrawn in view of the Amendment received on March 14, 2007.

The rejection of claims 25-27, 31-40, 55, and 56 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting the presence of a target myostatin variant nucleic acid sequence in a nucleic acid-containing specimen, wherein the specimen

Art Unit: 1637

is bovine, said bovine being Belgian Blue or Piedmontese, said specimen having increased muscle mass or having a predisposition for increased muscle mass as compared to said specimen having a wild-type myostatin nucleic acid sequence, said method comprising detecting the presence of the target myostatin variant nucleotide sequence, wherein the target myostatin variant nucleotide sequence is a deletion of nucleotides 937-947 in myostatin gene of Belgian Blue; or wherein the target myostatin variant nucleotide sequence is a G to A substitution at nucleotide position 1056 in myostatin gene of Piedmontese, wherein said variant nucleotide sequence is found in both alleles (homozygous), does not reasonably provide enablement for a method for detecting the presence of a target myostatin variant nucleic acid sequence in a nucleic acid specimen, wherein the specimen is avian, ovine, piscine, baboon, murine, or porcine, wherein the target myostatin variant nucleotide is any variant myostatin sequence, and wherein the variant sequence is found in only one allele (heterozygous), made in the Office Action mailed on September 15, 2006 is withdrawn in view of the Amendment received on March 14, 2007, amending the claims to the identified enabled embodiments.

The rejection of claims 66-70 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting the presence of a target myostatin variant nucleic acid sequence in a nucleic acid-containing specimen wherein the specimen is Belgian Blue and wherein the variant myostatin nucleotide sequence has a deletion of nucleotides 937-947 in the 3rd exon, not reasonably providing enablement for the method for detecting the presence of a target myostatin variant nucleic acid sequence in a nucleic acid-containing specimen, wherein the specimen is bovine, wherein the variant myostatin nucleotide sequence has a deletion of nucleotides 937-947 in the 3rd exon, made in the Office Action mailed on September 15, 2006 is withdrawn in view of the

Art Unit: 1637

Amendment received on March 14, 2007, amending the claims to the identified enabled embodiments.

The rejection of claims 34 and 35 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detection for Piedmontese myostatin variant nucleotide sequence having a homozygous G1056A substitution, wherein the probe hybridizes to SEQ ID Number 8, wherein the probe is SEQ ID Number 12, not reasonably providing enablement for the method wherein the probe hybridizes to SEQ ID Number 6, wherein the probe is SEQ ID Number 10, made in the Office Action mailed on September 15, 2006 is withdrawn in view of the Amendment received on March 14, 2007, amending the claims to the identified enabled embodiment.

Claim Rejections - 35 USC § 102

The rejection of claims 66-68 under 35 U.S.C. 102(e) as being anticipated by Grobet et al. (U.S. Patent No. 6,103,466, issued August 15, 2000, filed July 14, 1997), made in the Office Action mailed on September 15, 2006 is withdrawn in view of the Declaration received on January 22, 2007, entered as a result of the Amendment received on March 14, 2007, swearing behind the reference of record.

Claim Rejections - 35 USC § 103

The rejection of claims 43-46 under 35 U.S.C. 103(a) as being unpatentable over Grobet et al. (U.S. Patent No. 6,103,466, issued August 15, 2000, filed July 14, 1997), made in the Office Action mailed on September 15, 2006 is withdrawn in view of the Declaration received on January 22, 2007, entered as a result of the Amendment received on March 14, 2007. Since Grobet et al. is not prior art, the rejection must fall.

Art Unit: 1637

The rejection of claims 47-50, 69 under 35 U.S.C. 103(a) as being unpatentable over Grobet et al. (U.S. Patent No. 6,103,466, issued August 15, 2000, filed July 14, 1997) in view of Valent et al. (Molecular Microbiology, July 1997, vol. 25, no. 1, pages 53-64), made in the Office Action mailed on September 15, 2006 is withdrawn in view of the Declaration received on January 22, 2007, entered as a result of the Amendment received on March 14, 2007. Since Grobet et al. is not prior art, the rejection must fall.

Rejection, New Grounds

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meissner et al. (U.S. Patent No. 6,403,310, issued June 11, 2002, priority June 5, 1995).

Meissner et al. disclose a nucleic acid sequence comprising SEQ ID Number 3, which comprises the nucleotides 5' - TTGTGACAGA - 3', (see nucleotide position 171-180), which complements nucleotide 3' - AACACTGTCTTAG - 5' (underlined).

Claims 43, 45, and 46 are drawn to a product and the intended use recited in the preamble of the claims do not confer any patentable weight to the claimed product.

In the instant example, the nucleic acid sequence disclosed by Meissner et al. is fully capable of hybridizing to a target nucleic acid comprising SEQ ID NO: 6.

Hence, one of ordinary skill in the art, at the time the invention was made, employing the nucleic acid of Meissner et al., with the reagents commonly employed in sequencing or amplification

Art Unit: 1637

of nucleic acids (polymerase and dNTPs), so as to arrive at a kit for the conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, matched and/or preweighed components, etc, would render the instant claims obvious.

Applicants are advised to include the limitation of claim 44 into the base claim 43, so as to facilitate allowance of the entire application.¹

Applicants are also advised that incorporating the limitations imposed by claims 47 or 48, in to base claim 43 would facilitate allowance of the entire application.²

Conclusion

Claims 25-27, 31-35, 40, 49, 50, 55, 56, and 66-75 are allowed.

Claims 44, 47, 48 are objected to for being dependent on a rejected base claim.

The terminal disclaimer over U.S. Patent No. 6,673,534, received on January 22, 2007 has been approved.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

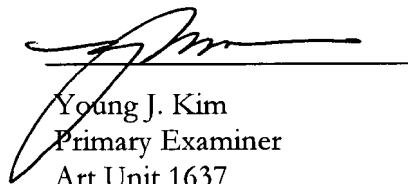
¹ SEQ ID NO: 6 and 8 are free of prior art.

² The presence of primers which hybridize to SEQ ID Numbers 1 and 2; or 3 and 4 in a kit format is also deemed non-obvious in view of the fact that a prior art reference must teach or render obvious a nucleic acid sequence comprising identity to at least SEQ ID Number 1 and 2; or SEQ ID Numbers 3 and 4; as well as a probe which shows homology to SEQ ID NO: 6 or 8, in a single kit format.

Art Unit: 1637

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.


Young J. Kim
Primary Examiner
Art Unit 1637
5/28/2007
YOUNG J. KIM
PRIMARY EXAMINER

YJK